

### **REMARKS**

Claims 1-25 were pending in the above-captioned application. Claims 1, 2, 4-25 have been amended herein, and claim 3 canceled, in order to expedite prosecution. Allowance of all claims 1, 2 and 4-25 is believed appropriate and is respectfully requested.

### **Claim Objections**

Claims 1-23 and 25 are objected to, as missing an “A” or “An” at the beginning of each claim. While not acquiescing in this objection, in the interest of expediting prosecution, “A” or “An” has been added to each claim, other than claim 22. With respect to claim 22, it is believed the plural of the preamble term “particles” makes the use of A or An improper. Withdrawal of this objection is believed appropriate.

Claims 6-10 and 12-25 are also objected to, as being multiple dependent claims which depend from at least one other multiple dependent claim. By amendment herein, no current claims have multiple dependency, and this objection should also be withdrawn.

### **Rejections Under 35 U.S.C. §112**

Claims 5 and 21 stand rejected under 35 U.S.C. §112, in that the use of the term “derivatives” is asserted to be unclear. While Applicants maintain that the noted term is well understood and accepted in the art, again in the interest of expediting

prosecution, the expression “and derivates thereof” has been deleted from claims 5 and 21 (with additional phraseology added to claim 21).

Claim 24 has been rejected under 35 U.S.C. §112, as well as under 35 U.S.C. §101 as a “use” claim depending from other claims, but not reciting any specific steps. Again, while not acquiescing in this rejection, claim 24 has been amended to specifically recite process steps; as such, the rejection of claim 24 under 35 U.S.C. §112 and 35 U.S.C. §101 should be withdrawn.

#### **Rejections Under 35 U.S.C. §103(a)**

Claims 1-5 and 11 stand rejected under 35 U.S.C. §103(a) over Gombotz (WO90/13780); however, it is submitted that the claims are inventive over Gombotz.

In Gombotz, the hollow micro porous structure is obtained after freeze-drying. It is the freeze-drying step which forms the “porous structure” – which is only said to be produced in Example 1 (page 11, lines 21-24). In contrast, the very low temperature obtained by freezing in the process of the present application weakens the resistance of the structure of the active principle rendering it more brittle. Thus, the expansion of the expansion agent caused by the cold medium increases the volume of the given form resulting in its fracture and the formation *in situ* of a porous structure without the requirement of a freeze-drying step.

In the present invention, removal of the expansion agent occurs during pore formation. The expansion agents used in the present invention have the ability to expand and have high vapor pressure characteristics.

It is submitted that Gombotz does not teach or suggest an expansion agent having an expansion coefficient greater than 5%. It will be noted that the present application, at paragraph 69, states that water cannot be considered to be an expansion agent as it has an expansion co-efficient close to 2%. Gombotz uses water as the "expansion agent." In contrast, the inventors of the above-captioned application have demonstrated that the carbonated water of the present invention is expanding due to presence of CO<sub>2</sub>, rather than water itself. It has been shown that if water is used as a solvent, it will not expand upon freezing with liquid nitrogen. Gombotz uses water to produce micro porous particles. It is suggested that it is the extraction medium (non-solvent) which results in the formation of micro porous particles. In the present invention, hollow micro porous particles are produced *in situ* as a result of the solvent expanding upon contact with the freezing medium.

If it would have been obvious to use an expansion agent, surely the Gombotz document would have stated that in an alternative embodiment, an expansion agent could have been employed in place of the non-solvent, so as to overcome the lengthy 3-day extraction time (see page 14).

The present invention also provides a number of inventive advantages. For example, as the expanding agent is removed during the pore producing process, the resultant micro porous particles are formed with interconnected pores. Furthermore, the process is flexible enough to form micro porous particles made purely of active principal if needed. In contrast Gombotz discloses the production of a microsphere which can only contain up to approximately 50% of active ingredient (page 5, line 27-29).

The particles produced by the present invention need not be of a uniform shape, but by selecting the appropriate expanding agent, they can be made to “explode” so as to form fragments of particles (as shown in Fig. 3 of the present application) if required.

A further advantage of the process is that the fractures can be formed on the surface of the particles which can assist in active principal delivery.

Lastly, the requirement of a freeze-drying step in Gombotz is both costly and time consuming and this step is not required in the present invention.

Accordingly, the rejections over Gombotz should be withdrawn.

### **CONCLUSION**

Based on the foregoing amendments and remarks, it is believed that allowance of all pending claims 1-2 and 4-25 is appropriate. Such action is earnestly sought. If there remains any matter which prevents the allowance of any of these claims, the Examiner is requested to call the undersigned collect at 615.242.2400 to arrange for an interview which may further expedite prosecution.

Applicants hereby petition the Commissioner for a three month extension of time to respond to the outstanding Office Action, extending the period for reply to August 20, 2008.

Respectfully submitted,

/James R. Cartiglia, Reg. No. 30,738/  
James R. Cartiglia  
Registration No. 30,738  
WADDEY & PATTERSON  
A Professional Corporation  
Customer No. 23456  
ATTORNEY FOR APPLICANT

James R. Cartiglia  
Waddey & Patterson  
Roundabout Plaza  
1600 Division Street, Suite 500  
Nashville, TN 37203  
(615) 242-2400